IN THE UNITED STATE DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

LOGAN ADLER ROTHSCHILD,	)	
	)	
Plaintiff,	)	
	)	**Civil Action No. _____**
v.	)	
	)	
COOK GROUP, INC., COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC., COOK MEDICAL, LLC, COOK INCORPORATED, MEDICAL ENGINEERING AND DEVELOPMENT INSTITUTE, INC., COOK MEDICAL TECHNOLOGIES, COOK DENMARK INTERNATIONAL APS, COOK DENMARK HOLDING APS, COOK GROUP EUROPE APS, COOK NEDERLAND BV, WILLIAM COOK EUROPE APS, MED INSTITUTE, INC., COOK MED INSTITUTE, INC.	)	**Jury Demand**
	)	
Defendant.	)	

COMPLAINT

INTRODUCTION

1. This is an action for damages against COOK GROUP, INC., COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC., COOK MEDICAL, LLC, COOK INCORPORATED, MEDICAL ENGINEERING AND DEVELOPMENT INSTITUTE, INC., COOK MEDICAL TECHNOLOGIES, COOK DENMARK INTERNATIONAL APS, COOK DENMARK HOLDING APS, COOK GROUP EUROPE APS, COOK NEDERLAND BV, WILLIAM COOK EUROPE APS, hereinafter collectively referred to as "Cook" and/or

"Defendants." The allegations, claims and theories of recovery relate to the Defendants' design, manufacture, sale, testing, marketing, labeling, advertising, promotion and/or distribution of its unsafe medical devices known as [Gunther Tulip Mreye, Gunther Tulip Vena Cava Filter, Cook Celect Vena Cava Filter, and Cook Celect Platinum] hereinafter "Cook IVC Filters" or "Cook's IVC Filters."

2. Cook IVC Filters are associated with, and cause, an increased risk for serious injury and death as a result of adverse events including: tilting, perforation, fracture, breakage and migration.

3. At all times relevant to this action, Cook intentionally, recklessly, and/or negligently failed to act as to the known failures and injuries associated with its devices and/or failed to warn about and concealed, suppressed, omitted, and/or misrepresented the risks, dangers, defects and disadvantages of its IVC Filters.

4. At all times relevant to this action, Cook intentionally, recklessly, and/or negligently advertised, labeled, promoted, marketed, sold and/or distributed its IVC Filters as a safe medical device when in fact Cook had reason to know, and/or did know, that its IVC Filters were not safe for its intended purposes, and that its IVC Filters caused serious injury and death.

5. At all times relevant to this action, Cook is and was strictly liable for injuries caused by its IVC Filters because the devices are unreasonably dangerous and not accompanied by adequate warnings about its danger.

PARTIES & JURISDICTION

6. Plaintiff Logan Rothschild is a citizen and resident of the State of Tennessee.

7. As a direct and proximate result of having Defendants' IVC Filters implanted in her, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into

the future. Plaintiff has lost her ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and have medical bills both past and future related to care because of the IVC filters' defects.

8. Defendant Cook Group, Incorporated is an Indiana Corporation with a principal place of business located at 750 Daniels Way, Bloomington, Indiana 47404. Defendant Cook Group, Incorporated regularly conducts business in the State of Illinois and Indiana, and is authorized to do so. Defendant Cook Group, Incorporated may be served with process upon its registered agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

9. Defendant Cook Group, Incorporated is the parent company of Defendant Cook Medical, Incorporated and is an Indiana Corporation with a principal place of business located at 750 Daniels Way, P.O. Box 489, Bloomington, Indiana 47402. Defendant Cook Group, Incorporated regularly conducts business in the State of Illinois and Indiana, and is authorized to do so. Defendant Cook Medical, Incorporated may be served with process upon its registered

agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

10. Defendant Cook Group, Inc. is the parent company of Defendant Cook Medical LLC and is an Indiana Corporation with a principal place of business located at 750 Daniels Way, P.O. Box 1608, Bloomington, Indiana 47402. Defendant Cook Group Incorporated regularly conducts business in the State of Illinois and Indiana, and is authorized to do so. Defendant Cook Medical, LLC may be served with process upon its registered agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

11. Defendant Cook Group, Inc. is the parent company of Defendant Cook Incorporated and is an Indiana Corporation with a principal place of business located at 750 Daniels Way, P.O. Box 1608, Bloomington, Indiana 47402. Defendant Cook Group Incorporated regularly conducts business in the State of Illinois and Indiana, and is authorized to do so. Defendant Cook Incorporated may be served with process upon its registered agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

12. Defendant Cook Group, Inc. is the parent company of Defendant Medical Engineering and Development Institute, Inc. and is an Indiana Corporation with a principal place of business located at 750 Daniels Way, P.O. Box 1608, Bloomington, Indiana 47402. Defendant Cook Group Incorporated regularly conducts business in the State of Illinois and Indiana, and is authorized to do so. Defendant Medical Engineering and Development Institute, Inc. may be served with process upon its registered agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

13. Defendant Cook Group, Inc. is the parent company of Defendant Cook Medical Technologies and is an Indiana Corporation with a principal place of business located at 750 Daniels Way, P.O. Box 1608, Bloomington, Indiana 47402. Defendant Cook Group, Inc. regularly conducts business in the State of Illinois and Indiana, and is authorized to do so. Defendant Cook Medical Technologies may be served with process upon its registered agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

14. Defendant Cook Group, Inc. is the parent company of Defendant Cook Denmark International APS and is an Indiana Corporation with a principal place of business located at 750 Daniels Way, P.O. Box 1608, Bloomington, Indiana 47402. Defendant Cook Group Incorporated regularly conducts business in the State of Illinois and Indiana, and is authorized to do so. Defendant Cook Denmark International APS may be served with process upon its registered agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

15. Defendant Cook Group, Inc. is the parent company of Defendant Cook Denmark Holding APS and is an Indiana Corporation with a principal place of business located at 750 Daniels Way, P.O. Box 1608, Bloomington, Indiana 47402. Defendant Cook Group Incorporated regularly conducts business in the State of Illinois and Indiana, and is authorized to do so. Defendant Cook Denmark Holding APS may be served with process upon its registered agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

16. Defendant Cook Group, Inc. is the parent company of Defendant Cook Group Europe APS and is an Indiana Corporation with a principal place of business located at 750

Daniels Way, P.O. Box 1608, Bloomington, Indiana 47402. Defendant Cook Group Incorporated regularly conducts business in the State of Illinois and Indiana, and is authorized to do so. Defendant Cook Group Europe APS may be served with process upon its registered agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

17. Defendant Cook Group, Inc. is the parent company of Defendant Cook Nederland BV and is an Indiana Corporation with a principal place of business located at 750 Daniels Way, P.O. Box 1608, Bloomington, Indiana 47402. Defendant Cook Group Incorporated regularly conducts business in the State of Illinois and Indiana, and is authorized to do so. Defendant Cook Nederland BV may be served with process upon its registered agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

18. Defendant William Cook Europe APS is based in Bjaeverskov, Denmark and regularly conducts business in the State of Illinois and Indiana, and is authorized to do so. Defendant William Cook Europe APS may be served with process upon its registered agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

19. Defendants MED Institute, Inc. and Cook MED Institute, Inc., (MED = Medical Engineering and Development) are Indiana Corporations with principal places of business located at 1 Geddes Way, West Lafayette, Indiana 47906 and are subject to the jurisdiction of this Court. Defendants MED Institute, Inc. and Cook MED Institute, Inc., regularly conduct business in the United States to include the State of Georgia and are authorized to do so. Defendants MED Institute, Inc. and Cook MED Institute, Inc. may be served with process upon

their registered agent for service: C/O Corporation Service Company, 251 East Ohio Street, Suite 500, Indianapolis, IN 46204.

20. At all times alleged herein, the Cook defendants include any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

21. Cook develops, manufactures, sells and distributes medical devices for use in various medical applications including endovascular cardiology, and surgical products throughout the United States and around the world. Cook's products at issue in this matter include the Gunther Tulip Mreye, Gunther Tulip Vena Cava Filter, Cook Celect Vena Cava Filter, and the Cook Celect Platinum all of which are used for the prevention of recurrent pulmonary embolism via placement in the vena cava.

22. At all times relevant, Cook was engaged in the business of researching, designing, testing, developing, manufacturing, packaging, labeling, marketing, advertising, distributing, promoting, warranting and selling in interstate commerce, its IVC Filters either directly or indirectly through third parties or related entities.

23. This Court has subject matter jurisdiction under 28 U.S.C. § 1332 because the Plaintiff and the Defendants are citizens of different states, and the amount in controversy exceeds seventy-five thousand dollars ($75,000.00), excluding interest and costs and there is complete diversity of citizenship between Plaintiff and Defendants.

24. At all times relevant, Defendants regularly conducted substantial business in the State of Tennessee.

25. At all times relevant, Defendants transacted, solicited, and conducted business in

Tennessee through their employees, agents, borrowed servants and/or sales representatives, and derived substantial business from such business and/or contacts.

26. At all times relevant, Defendants placed defective devices and products into the stream of interstate commerce, and these defective devices and products were implanted into Ms. Rothschild.

27. Defendants are subject to *in personam* jurisdiction in Tennessee under the Tennessee Long-Arm Statute, Tenn. Code Ann. § 20-2-214 (2012), because of the activity conducted therein. Defendants' activities in each state include: marketing, advertising, promoting, distributing, and receiving substantial compensation and profits from sales and other acts that caused or contributed to the harm giving rise to this action. Defendants also made or caused to be made material omissions and misrepresentations and breaches of warranties in Tennessee.

VENUE

28. Venue properly lies in the Middle District of Tennessee pursuant to 28 U.S.C.A. §§ 1391(a) and (c), as a substantial number of the events, actions or omissions giving rise to Plaintiff's claims occurred in this District.

FACTUAL BACKGROUND

29. Defendants design, research, develop, manufacturer, test, market, advertise, promote, distribute, and sell products that are sold to and marketed to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava. Defendants' products

include, the Cook Celect Vena Cava Filter and the Gunther Tulip Filter (collectively referred to herein as "Cook Filters"), which are introduced via a coaxial introducer sheath system.

30. Defendants sought Food and Drug Administration ("FDA") approval to market the Cook Filters and/or its components under Section 510(k) of the Medical Device Amendment.

31. Section 510(k) allows marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the said device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" process in an amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp*., 376 F.3d 163, 167 (3d Cir. 2004):

> A manufacturer can obtain an FDA finding of "substantial equivalence" by submitting a premarket notification to the agency in accordance with section 510(k)…A device found to be 'substantially equivalent' to a predicate device is said to be "cleared" by FDA (as opposed to "approved" by the agency under a [premarket approval]). A pre-market notification submitted under 510(k) is thus entirely different from a [pre-market approval] which must include data sufficient to demonstrate that the device is safe and effective. (Emphasis in original).

32. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470,478-79 (1996), the Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] §510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis…The §510(k) notification process is by no means comparable to the [premarket approval] process; in contract to the 1,200 hours necessary to complete a PMA review, the §510(k) review is completed in average of 20 hours…Section §510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets process quickly.

33. An IVC filter, like the Cook Filters, is a device designed to filter blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC

filters may be designed to be implanted, either temporarily or permanently, within the vena cava.

34. The inferior vena cava is a vein that returns blood to the heart from the lower portion of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava into the lungs. Often these thrombi develop in the deep leg veins. The thrombi are called "deep vein thrombosis" or DVT. Once the thrombi reach the lungs they are considered "pulmonary emboli" or PE. An IVC filter, like the Cook IVC Filters, is designed to prevent thromboembolic events.

35. The Cook Filters are retrievable filters.

36. The Cook Celect® Vena Cava Filter has four (4) anchoring struts for fixation and eight (8) independent secondary struts to improve self-centering and clot trapping.

37. The Gunther Tulip® Vena Cava Filter has a top hook and (4) anchoring struts for fixation and on each strut, it has a "flower" formation that is shorter than the strut where a wire piece branches out on each side of the strut forming an overall "flower" type formation on each strut.

38. At all times relevant hereto, the Cook Filters were widely advertised and promoted by the Defendants as safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava. At all times relevant hereto, Defendants knew its Cook Filters were defective and knew that defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

39. A retrospective review of all Cook Gunther Tulip Filters and Cook Celect filters retrieved between July 2006 and February 2008 was performed. One hundred and thirty (130) filter retrievals were attempted but in 33 cases, the standard retrieval technique failed. The

authors concluded that "unsuccessful retrieval was due to significant endothelialization and caval penetration" and that "hook endothelialization is the main factor resulting in failed retrieval and continues to be a limitation with these filters." O. Doody, et al.; "Assessment of Snared-Loop Technique When Standard Retrieval of Inferior Vena Cava Filters Fail" Cardiovasc Intervent Radiol (Sept 4, 2008 Technical Note).

40. A retrospective review of 115 patients who underwent Cook Celect IVC filter insertion between December 2005 and October 2007 was performed. While filter insertion was successful in all patients, the authors also concluded that "[f]ailed retrieval secondary to hook endothelialization continues to be an issue with this filter." O. Doody, et al; Journal of Medical Imaging and Radiation Oncology "Initial Experience in 115 patients with the retrievable Cook Celect vena cava filter" 53 (2009) 64-68 (original article).

41. In a review of clinical data related to 73 patients who had Celect IVC filter implanted between August 2007 and June 2008, the authors found that the Celect IVC filter was related to a high incidence of caval filter leg penetration. Immediately after fluoroscopy-guided filter deployment in 61 patients, four filters (6.5%) showed significant tilt. Follow-up abdominal CT in 18 patients demonstrated filter related problems in 7 (39%), which included penetration of filter legs in 4 and fracture/migration of filter components in 1.

42. In a study of Gunther Tulip and Celect IVC filters implanted between July 2007 and May of 2009 reported by Cardiovascular Interventional Radiology electronically on March 30, 2011 and published by journal in April 2012, one hundred percent of the Cook Celect filters and Gunther Tulip filters imaged after 71 days of implant caused some degree of filter perforation of the venal caval wall. Durack JC, et al, Cardiovasc Intervent Radiol., "Perforation of the IVC: rule rather than the exception after longer indwelling times for the Gunther Tulip and Celect Retrievable Filters," 2012 Apr.; 35(2):299-308. Epub 2011 Mar 30. The authors

concluded: "Although infrequently reported in the clinical literature, clinical sequelae from IVC filter components breaching the vena cava can be significant." Defendants knew or should have known that their IVC filters were more likely than not to perforate the vena cava wall.

43. This same study reported that tilt was seen in 20 out of 50 (40%) of the implanted Gunther Tulip and Celect IVC filters and all tilted filters also demonstrated vena caval perforation. Defendants knew or should have known that their IVC filters were more likely than not tilt and to perforate.

44. While not inclusive of all medical studies published during the relevant time period, the above references show that the Defendants failed to disclose to physicians, patients and/or Plaintiff that its Cook Filters were subject to breakage, tilt, inability of removal, and migration even though they knew or should have known the same was true**.**

45. At all times relevant hereto, the Defendants continued to promote the Cook Filter as safe and effective even when inadequate clinical trials had been performed to support long or short to safety and/or efficacy.

46. The Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Cook Filters, as aforesaid.

47. The Cook Filters are constructed of conichrome.

48. The Defendants specifically advertise the conichrome construction of the filter as a frame which "reduces the risk of fracture."

49. The failure of the Cook Filters is attributable, in part, to the fact that the Cook Filters suffer from a design defect causing it to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo.*

50. At all times relevant hereto, the Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Cook Filters, including, but not limited to the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

51. The Cook Filters were designed, manufactured, distributed, sold and/or supplied by the Defendants, and were marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Defendants' knowledge of the products' failure and serious adverse events.

52. That at all times relevant hereto, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew or should have known of the hazardous and dangerous propensities of the said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

53. Plaintiff (Logan Adler Rothschild) was implanted with the Gunther Tulip filter, lot number/serial number 2176016, model number G33016, item number 39401, during a surgery performed by Raul J. Guzman, M.D., at Vanderbilt University Medical Center on January 9, 2009.

54. The product was implanted in Ms. Rothschild for future pulmonary embolism prohylaxis, the uses for which the Cook IVC Filters were designed, marketed and sold.

55. The product failed despite appropriate implantation and use by Ms. Rothschild and her healthcare providers.

56. On May 13, 2016, removal of the Cook IVC Filter was attempted during a surgery performed by Clifford Garrard, M.D. at Vanderbilt University Medical Center; however, the

filter could not be removed because it was embedded in the vena caval wall necessitating a second surgical procedure to remove the filter on June 6, 2016, by Peter Bream, M.D. at Vanderbilt University Medical Center.

57. As a direct and proximate result of having Defendants' IVC Filter implanted in her, Ms. Rothschild has suffered significant damages, including but not limited to permanent physical injury, economic loss, pain and suffering and the need for additional procedures to repair the physical damage to Ms. Rothschild caused by the product.

COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN

58. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

59. Cook IVC Filters were defective and unreasonably dangerous when they left the possession of the Defendants in that they contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

60. Information provided by Cook to the medical community and to consumers concerning the safety and efficacy of its IVC Filters did not accurately reflect the serious and potentially fatal adverse events Plaintiff could suffer.

61. At all times relevant hereto, the Cook IVC Filters were dangerous and presented a substantial danger to patients who were implanted with the Cook IVC Filters, and these risks and dangers were known or knowable at the times of distribution and implantation in Plaintiff. Ordinary consumers would not have recognized the potential risks and dangers the Cook IVC Filters posed to patients, because their use was specifically promoted to improve health of such patients.

62. Had adequate warnings and instructions been provided, Plaintiff would not have been implanted with Cook IVC Filters, and would not have been at risk of the harmful injuries described herein. The Defendants failed to provide warnings of such risks and dangers to the Plaintiff and their medical providers as described herein. Neither Plaintiff, nor Plaintiff's physicians knew, nor could they have learned through the exercise of reasonable care, the risks of serious injury and/or death associated with and/or caused by Cooks' IVC Filters.

63. Defendants knew or had knowledge that the warnings that were given failed to properly warn of the increased risks of serious injury and/or death associated with and/or caused by Cook IVC Filters.

64. Plaintiff, individually and through her implanting physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

65. Defendants had a continuing duty to warn Plaintiff and her physicians of the dangers associated with the subject products.

66. Safer alternatives were available that were effective and without risks posed by Cooks' IVC Filters.

67. As a direct and proximate result of the Cook IVC Filters' defects, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost her ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and have medical bills, both past and future, related to care because of the Cook IVC Filters' defects.

68. By reason of the foregoing, Defendants are liable to Plaintiff for damages as a result of their failure to warn and/or adequately warn the Plaintiff and healthcare professionals about the increased risk of serious injury and death caused by their defective IVC filters.

69. **WHEREFORE,** Plaintiff demands judgment against the Cook Defendants and seek damages as detailed in the Global Prayer of Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT II: STRICT PRODUCTS LIABILITY – DESIGN DEFECT

70. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

71. Defendants have a duty to provide adequate warnings and instructions for their products including their IVC Filters, to use reasonable care to design a product that is not unreasonably dangerous to users.

72. At all times relevant to this action, Defendants designed, tested, manufactured, packaged, labeled, marketed, distributed, promoted and sold their IVC Filters, placing the devices into the stream of commerce.

73. At all times relevant to this action, Cook's IVC Filters were designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendants in a condition that was defective and unreasonably dangerous to consumers, including Plaintiff.

74. Cook IVC Filters are defective in their design and/or formulation in that they are not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with their design and formulation.

75. Cook IVC Filters were expected to reach, and did reach, users and/or consumers including Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which they were manufactured and sold.

76. Physicians implanted as instructed via the Instructions for Use and in a foreseeable manner as normally intended, recommended, promoted, and marketed by the Defendants. Plaintiff received and utilized Cook IVC Filters in a foreseeable manner as normally intended recommend, promoted, and marketed by the Defendants.

77. Cook IVC Filters were and are unreasonably dangerous in that, as designed, failed to perform safely when used by ordinary consumers, including Plaintiff, including when the filters were used as intended and in a reasonably foreseeable manner.

78. Cook IVC Filters were and are unreasonably dangerous and defective in design or formulation for their intended use in that, when they left the hands of the manufacturers and/or supplier, they posed a risk of serious vascular and other serious injury which could have

been reduced or avoided, inter alia, by the adoption of a feasible reasonable alternative design. There were safer alternative designs for the like products.

79. Cook IVC Filters were insufficiently tested and caused harmful adverse events that outweighed any potential utility.

80. Cook IVC Filters, as manufactured and supplied, were defective due to inadequate warnings, and/or inadequate clinical trials, testing, and study, and inadequate reporting regarding the results of the clinical trials, testing and study.

81. Cook IVC Filters, as manufactured and supplied, were defective due to its no longer being substantially equivalent to its predicate device with regard to safety and effectiveness.

82. Cook IVC Filters as manufactured and supplied by the Defendants are and were defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of injuries from use and acquired additional knowledge and information confirming the defective and dangerous nature of its IVC Filters, Defendants failed to provide adequate warnings to the medical community and the consumers, to whom Defendants were directly marketing and advertising; and further, Defendants continued to affirmatively promote their IVC Filters as safe and effective and as safe and effective as their predicate device.

83. As a direct and proximate result of the Cook IVC Filters' defects, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost their ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose

earnings into the future and has medical bills both past and future related to care because of the IVC filter's defect.

84. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of their failure to warn and/or adequately warn the Plaintiff and healthcare professionals about the increased risk of serious injury and death caused by their defective IVC filters.

85. **WHEREFORE,** Plaintiff demands judgment against the Cook Defendants and seek damages as detailed in the Global Prayer of Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT III: NEGLIGENCE

86. Plaintiff repeats and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

87. At all times relevant to this cause of action, the Cook Defendants were in the business of designing, developing, manufacturing, marketing and selling sophisticated medical devices, including its Cook IVC Filters.

88. At all times relevant hereto, the Cook Defendants were under a duty to act reasonably to design, develop, manufacture, market and sell a product that did not present a risk of harm or injury to the Plaintiff and to those people receiving their IVC Filters.

89. At the time of manufacture and sale of the Cook IVC Filters, the Cook Defendants knew or reasonably should have known the Cook IVC Filters:

a. were designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device, as aforesaid;

b. were designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device, as aforesaid;

c. were designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body; and/or

d. were designed and manufactured so as to present an unreasonable risk of perforation and damage to the vena caval wall.

90. Despite the aforementioned duty on the part of the Cook Defendants, they committed one or more breaches of their duty of reasonable care and were negligent in:

a. unreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with the Cook IVC Filters, specifically its incidents fracture, migration, perforation and other failure;

b. unreasonably and carelessly manufacturing a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body;

c. unreasonably and carelessly designed a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body; and

d. unreasonably and carelessly designed a product that presented a risk of harm to the Plaintiff and others similarly situated in that it was prone to fail.

91. As a direct and proximate result of the Cook IVC Filters' defects, as described herein, Plaintiff suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost her ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and has medical bills both past and future related to care because of the Cook IVC Filters' defects.

92. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of their failure to warn and/or adequately warn the Plaintiff and healthcare professionals about the increased risk of serious injury and death caused by their defective IVC filters.

93. **WHEREFORE,** Plaintiff demands judgment against the Cook Defendants and seek damages as detailed in the Global Prayer of Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper; further,

COUNT IV: NEGLIGENCE PER SE

(Violation of 21 U.S.C. §§321, 331, 352 and 21 C.F.R. §§1.21, 801, 803, 807, 820)

94. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

95. At all times herein mentioned, Defendants had an obligation not to violate the law, including the Federal Food, Drug and Cosmetic Act and the applicable regulations, in the manufacture, design, testing, production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, promotion, labeling, packaging, preparation for use, consulting, sale, warning and post-sale warning and other communications of the risks and dangers of Cook IVC Filters.

96. By reason of its conduct as alleged herein, Cook violated provisions of statutes and regulations, including but not limited to, the following:

a. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§331 and 352, by misbranding its Cook IVC Filters;

b. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321 in making statements and/or representations via word, design, device or

any combination thereof failing to reveal material facts with respect to the consequences that may result from the use of Cook IVC Filters to which the labeling and advertising relates;

c. Defendants violated the 21 C.F.R. §1.21 in misleading the consumers and patients by concealing material facts in light of representations made regarding safety and efficacy of its Cook IVC Filters;

d. Defendants violated the 21 C.F.R. §801 in mislabeling its Cook IVF Filters as to safety and effectiveness of its products and by failing to update its label to reflect post-marketing evidence that Cook IVC Filters were associated with an increased risk of injuries due to tilting, fracture, migration and perforation;

e. Defendants violated the 21 C.F.R. §803 by not maintaining accurate medical device reports regarding adverse events of tilting, fracture, migration and perforation and/or misreporting these adverse events maintained via the medical device reporting system;

f. Defendants violated the 21 C.F.R. §807 by failing to notify the FDA and/or the consuming public when its Cook IVC Filters were no longer substantially equivalent with regard to safety and efficacy with regard to post-marketing adverse events and safety signals; and

g. Defendants violated the 21 C.F.R. §820 by failing to maintain adequate quality systems regulation including, but not limited to, instituting effective corrective and preventative actions,

97. **WHEREFORE**, Plaintiff demands judgment against the Cook Defendants and seek damages as detailed in the Global Prayer of Relief including: compensatory damages,

exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other an further relief as this Court deems just and proper; further,

COUNT V: BREACH OF EXPRESS WARRANTY

98. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action. Plaintiff, though her medical providers, purchased Cook IVC Filters from the Cook Defendants.

99. At all times to this cause of action, the Cook Defendants were merchants of goods of the kind including medical devices and vena cava filters (i.e., Cook IVC Filters).

100. At the time and place of sale, distribution and supply of the Cook IVC Filters to Plaintiff (and to other consumer and the medical community), the Defendants expressly represented and warranted in their marketing materials, both written and orally, and in the IFUs, that the Cook IVC Filters were safe, well-tolerated, efficacious, and fit for their intended purpose and were of marketable quality, that they did not produce any unwarned-of dangerous side effects, and that they were adequately tested.

101. At the time of Plaintiff's purchase from Defendants, the Cook IVC Filters were not in a merchantable condition and Defendants breached their expressed warranties, in that the filters:

a. were designed in such a manner so as to be prone to a unreasonably high incident of fracture, perforation of vessels and organs, and/or migration;

b. were designed in such a manner so as to result in a unreasonably high incident of injury to the organs of its purchaser; and

c. were manufactured in such a manner so that the exterior surface of the Cook Filters were inadequately, improperly and inappropriately designed causing the device to weaken and fail.

102. As a direct and proximate result of the Cook IVC Filters' defects, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability, and impairment. Plaintiff has suffered emotional trauma, harm, and injuries that will continue into the future. Plaintiff has lost their ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and have medical bills both past and future related to care because of the IVC filters' defect.

103. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of their breach express warranty.

104. **WHEREFORE,** Plaintiff demands judgment against the Cook Defendants and seek damages as detailed in the Global Prayer of Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper; further,

COUNT VI: BREACH OF IMPLIED WARRANTY

105. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

106. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold its IVC Filters.

107. At all relevant times, the Defendants intended its IVC Filters be used in the manner that Plaintiff in fact used them.

108. Defendants impliedly warranted their IVC Filters to be of merchantable quality, safe and fit for the use for which the Defendants intended them and for which Plaintiff in fact used them.

109. Defendants breached their implied warranties as follows:

a. Defendants failed to provide the warning or instruction and/or an adequate warning or instruction which a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that its Cook IVC Filters would cause harm;

b. Defendants manufactured and/or sold their Cook IVC Filters and said filters did not conform to representations made by the Defendants when they left the Defendants' control;

c. Defendants manufactured and/or sold their Cook IVC Filters which were more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, and the foreseeable risks associated with the Cook Filters' design or formulation exceeded the benefits associated with that design. These defects existed at the time the products left the Defendants' control; and

d. Defendants manufactured and/or sold their Cook IVC Filters when they deviated in a material way from the design specifications, formulas or performance standards or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards, and these defects existed at the time the products left the Defendants' control.

110. Further, Defendants' marketing of their Cook IVC Filters was false and/or misleading.

111. Plaintiff, through her attending physicians, relied on these representations in determining which IVC filter to use for implantation in the Plaintiff.

112. Defendants' filters were unfit and unsafe for use by users as they posed an unreasonable and extreme risk of injury to persons using said products, and accordingly Defendants breached their expressed warranties and the implied warranties associated with the product.

113. The foregoing warranty breaches were a substantial factor in causing Plaintiff's injuries and damages as alleged.

114. As a direct and proximate result of the Cook IVC Filters' defects, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost their ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and has medical bills both past and future related to care because of the IVC filters' defects.

115. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of its breaches of implied warranty.

116. **WHEREFORE,** Plaintiff demands judgment against the Cook Defendants and seek damages as detailed in the Global Prayer of Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other an further relief as this Court deems just and proper; further,

COUNT VII: VIOLATIONS OF APPLICABLE STATE LAW PROHIBITING CONSUMER FRAUD AND UNFAIR AND DECEPTIVE TRADE PRACTICES

117. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

118. Defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the sale and promotion of Cook's IVC Filters to Plaintiff.

119. Defendants engaged in unfair, unconscionable, deceptive, fraudulent and misleading acts or practices in violation of the State of Tennessee's consumer protection laws, identified below.

120. Through its false, untrue and misleading promotion of Cook's IVC Filters, Defendants induced Plaintiff to purchase and/or pay for the purchase of Cook's IVC Filters.

121. Defendants misrepresented the alleged benefits and characteristics of Cook's IVC Filters; suppressed, omitted, concealed, and failed to disclose material information concerning known adverse effects of Cook's IVC Filters; misrepresented the quality and efficacy of Cook's IVC Filters as compared to much lower-cost alternatives; misrepresented and advertised that Cook's IVC Filters were of a particular standard, quality, or grade that they were not; misrepresented Cook's IVC Filters in such a manner that later, on disclosure of the true facts, there was a likelihood that Plaintiff would have opted for an alternative IVC Filter or method of preventing pulmonary emboli.

122. Defendants' conduct created a likelihood of, and in fact caused, confusion and misunderstanding. Defendants' conduct misled, deceived, and damaged Plaintiff, and Defendants' fraudulent, misleading, and deceptive conduct was perpetrated with an intent that Plaintiff rely on said conduct by purchasing and/or paying for purchases of Cook's IVC

Filters. Moreover, Defendants knowingly took advantage of Plaintiff, who was reasonably unable to protect their interests due to ignorance of the harmful adverse effects of Cook's IVC Filters.

123. Defendants' conduct was willful, outrageous, immoral, unethical, oppressive, unscrupulous, unconscionable, and substantially injurious to Plaintiff and offends the public conscience.

124. Plaintiff purchased Cook's IVC Filters primarily for personal, family, or household purposes.

125. As a result of Defendants' violative conduct in Plaintiff's respective state, Plaintiff purchased and/or paid for purchases of Cook IVC Filters that were not made for resale.

126. Defendants engaged in unfair competition or deceptive acts or practices in violation of Tenn. Code Ann. § 47-18-104, *et seq*.

127. **WHEREFORE,** Plaintiff demands judgment against the Cook Defendants and seek damages as detailed in the Global Prayer of Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper; further,

COUNT VIII: UNJUST ENRICHMENT

128. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

129. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from the purchase of Defendants' filter by Plaintiff.

130. Defendants have voluntarily accepted and retained these profits and benefits, derived from Plaintiffs, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiff was not receiving a product of the

quality, nature or fitness that had been represented by Defendants or that Plaintiff, as reasonable consumer, expected.

131. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of Plaintiffs, who are entitled to in equity, and hereby seek, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the Defendants' unjust enrichment.

COUNT IX: PUNITIVE DAMAGES

132. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

133. At all times material hereto, Defendants knew or should have known that their Cook IVC Filters were inherently dangerous with respect to the risk of tilt, fracture, migration and/or perforation.

134. At all times material hereto, Defendants attempted to misrepresent and did knowingly misrepresent facts concerning the safety of their Cook IVC Filters.

135. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff's physicians, concerning the safety of their Cook IVC Filters. The Defendants' conduct was willful, wanton, and undertaken with a conscious indifference to the consequences that consumers of their product faced, including Plaintiff.

136. At all times material hereto, Defendants knew and recklessly disregarded the fact that their Cook IVC Filters have an unreasonably high rate of tilt, fracture, migration and/or perforation.

137. Notwithstanding the foregoing, Defendants continued to market their Cook IVC

Filters aggressively to consumers, including Plaintiff, without disclosing the aforesaid side effects.

138. Defendants knew of their IVC Filters' lack of warnings regarding the risk of fracture, migration, and/or perforation, but intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and sell their Filters without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious disregard of the foreseeable harm caused by Cook's IVC Filters.

139. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff's physicians of necessary information to enable them to weigh the true risks of using Cook IVC Filters against their benefits.

140. As a direct and proximate result of Defendants' willful, wanton, careless, reckless, conscious, and deliberate disregard for the safety and rights of consumers including Plaintiff, Plaintiff has suffered and will continue to suffer severe and permanent physical and emotional injuries, as described with particularity, above. Plaintiff has endured and will continue to endure pain, suffering, and loss of enjoyment of life; and have suffered and will continue to suffer economic loss, including incurring significant expenses for medical care and treatment and lost wages.

141. Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the safety and rights of consumers including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

DISCOVERY RULE AND TOLLING OF THE LIMITATIONS PERIOD

142. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

143. Plaintiff avers that it was not until January of 2016 that she was aware of any issues regarding any IVC filters and it was not discovered that an injury, wrong or breach of duty had occurred (or that the issues included products implanted in Ms. Rothschild) until after Plaintiff received subsequent information from her physicians and/or healthcare providers.

144. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

145. Plaintiff pleads that the Tennessee discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

146. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with her medical providers, the nature of her injuries and damages, and their relationship to the Products was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

147. Defendants, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's healthcare providers the true and significant risks associated with Cook's IVC Filters.

148. As a result of Defendants' actions, Plaintiff and her prescribing physicians were

unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the result of Defendants' acts, omissions, and misrepresentations.

149. Accordingly, no limitations period ought to accrue until such time as Plaintiff knew or reasonably should have known of some causal connection between Plaintiff being implanted with a Cook IVC Filter and the harm Plaintiff suffered as a result.

150. Additionally, the running of the statute of limitations in this cause is tolled due to equitable tolling. Defendant(s) are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and Plaintiff's physicians of the true risks associated with the Cook IVC Filters. As a result of Defendants' fraudulent concealment, Plaintiff and her physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendant(s).

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff demands judgment against the Cook Defendants as follows:

A. Compensatory damages, including without limitation past and future medical expenses; past and future pain and suffering; past and future emotional distress; past and future

loss of enjoyment of life; past and future lost wages and loss of earning capacity; funeral and burial expenses; and consequential damages;

B. Punitive damages in an amount sufficient to punish Defendants and set an example;

C. Disgorgement of profits;

D. Restitution;

E. Costs and fees of this action, including reasonable attorney's fees;

F. Prejudgment interest and all other interest recoverable; and

G. Such other additional and further relief as Plaintiff may be entitled to in law or in equity according to the claims pled herein.

DEMAND FOR JURY TRIAL

Plaintiff respectfully requests trial by jury in the above case as to all issues.

Respectfully submitted,

DAVID RANDOLPH SMITH & ASSOCIATES

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